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K003184
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510(k) Summary

28 September 2000

Submitted by: Friedel MW Zander
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Manufactured by: RS Biotech
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Contact: A. Malcolm McNab
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Prepared by: Friedel MW Zander
Zander Medical Supplies, Inc.

Trade Name: RS Biotech Galaxy 'R' CO2 Incubator
#170-300 ----- 220/240v 50/60Hz
#170-301 ----- 100/120v 50/60Hz

Common Name: Galaxy 'R'

Class: II **CFR:** 884.6120 **Procode:** 85 MQG

Predicate Device: Hoffman IVF-1
K991216
August 5, 1999

Description

The Galaxy 'R' is an incubator used for maintaining the proper temperature and pH levels for biological cultures of embryos, oocytes and similar matter.

Technical Specifications

Temperature Management:

Digital programming via microprocessor control in 0.1°C increments. Measurement of chamber and outer door temperature via 4RT matched thermistors (sensitity 0.01°C). "Out of Limits" remperature protection system independent of microprocessor control.

Range:	1°C above ambient temperature to +50°C
Control:	+/- 0.1°C
Stability:	+/- 0.1°C
Uniformity:	+/- 0.2°C

Relative Humidity:

Standard stainless steel humidity reservoir:

Reservoir capacity:	1.5 litres
Relative humidity:	95% at 37°C

Large humidity reservoir:

Reservoir capacity:	2.5 litres
Relative humidity:	98% at 37°C

Shelves:

Polished stainless steel – perforated.

Capacity:	0.25m²/shelf
Standard No:	3 (maximum 8)
Adjustable in:	15 steps

Technical Specifications (cont'd)

CO2 Control:

Solid state infra-red CO2 sensor which operates independent of humidity. Auto zeroing facility.

Range:	0.2 – 10% or 0.2 – 20%
Control:	+/- 0.1%
Stability:	+/- 0.2%
Uniformity:	+/- 0.1%
Recovery rate:	Better than 0.7% per minute
Gas connections:	6mm tubing
Required gas pressure:	0.35 bar / 5psi

Dimensions:

Chamber:	570 x 525 x 570 mm
External:	745 x 600 x 650 mm
Weight:	70 kg
Chamber volume:	170 litres

Electrical Supply:

Voltage:	100-120 v 50/60 Hz or 220-240 v 50/60 Hz
Power:	500 watts – Standard models 1,000 watts – High temperature decontamination models. Energy required to maintain chamber at 37°C – under 0.1kwh

Alarm Systems:

Two level alarm system giving programmable audio visual warnings with option for remote communication. Level 1 signals system failures, Level 2 is programmable and monitors chamber conditions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2000

Mr. Friedel MW Zander
President/CEO
Zander Medical Supplies
755 - 8th Court, Suite #4
P.O. Box 650790
VERO BEACH FL 32965-0790

Re: K003184
RS Biotech Galaxy 'R' CO_2 Incubator
Dated: October 9, 2000
Received: October 11, 2000
Regulatory Class: II
21 CFR §884.6120/Procode: 85 MQG

Dear Mr. Zander:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) NUMBER (IF KNOWN): K003184

DEVICE NAME: RS Biotech Galaxy 'R' CO_2 Incubator

INDICATIONS FOR USE:

The Galaxy 'R' is an incubator used for maintaining the proper temperature and pH levels for biological cultures of embryos, oocytes and similar matter.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ~~ANOTHER PAGE~~ IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003184